

## **REMARKS**

The undersigned thanks Examiner Webb for her thorough review of the present application.

In a 3 June 2004 non-final Office Action (the "Office Action"), the Examiner noted the restriction requirement issued and provisional election made in a 24 May 2004 teleconference, provisionally rejected claims 1 – 20 under the judicially created doctrine of obviousness-type double patenting, rejected claims 1 – 6, 8, 10 – 14 and 16 under 35 U.S.C. §102(b) as anticipated by U.S.P.N. 5,682,886 ("Delp et al."), rejected claims 15 and 17 under 35 U.S.C. §103(a) as unpatentable over Delp et al. in view of U.S.P.N. 5,733,292 ("Gustilo et al."), and rejected claims 9 and 18 – 20 under §103(a) as unpatentable over Delp et al. in view of U.S.P.N. 6,226,548 ("Foley et al."). Upon entry of the above amendment, claims 1 – 29 are pending, claims 1, 7 and 8 are amended and claims 21 – 29 are withdrawn from consideration. No new matter has been added by this amendments. Based on the following remarks and above amendments, the undersigned respectfully requests reconsideration and allowance of all pending claims.

## **RESTRICTION REQUIREMENT**

In response to the restriction requirement discussed in the 24 May 2004 teleconference and detailed on page 2 of the Office Action, the undersigned hereby affirms the election of Group I, claims 1 – 20.

## **DOUBLE PATENTING REJECTION**

The Office Action, on page 3, provisionally rejected under the judicially created doctrine of obviousness-type double patenting claims 1 – 20, as unpatentable over claims 1 – 20 of Application No. 10/084,278.

Along with this amendment and response, the undersigned submits a terminal disclaimer in compliance with 37 C.F.R. §1.321(c) executed by the attorney of

record. The undersigned believes that the submitted terminal disclaimer overcomes the provisional double patenting rejection and respectfully requests the Examiner to withdraw the same.

## §102 REJECTIONS

The Office Action, on pages 4 – 5, rejected claims 1 – 6, 8, 10 – 14 and 16 as anticipated by Delp et al. Applicants respectfully traverse this rejection and requests reconsideration and withdrawal thereof.

To anticipate a claim, a reference must teach each and every element of the claim, either expressly or inherently. See M.P.E.P. § 2131. Delp et al. does not teach each and every element of the rejected claims.

Claim 1, as currently amended, requires a process for performing total knee arthroplasty that includes the step of “registering a total knee arthroplasty surgical instrument attached to a fiducial....” Therefore claims 2 – 6, 8 and 10 – 14, which all depend from claim 1, also all require “registering a total knee arthroplasty surgical instrument attached to a fiducial....” Delp et al. does not teach attaching a fiducial to a total knee arthroplasty surgical instrument.

Rather, Delp et al. discloses attaching a robotic arm (referred to in Delp et al. as a CMM) to various jigs, including a femoral jig and a tibial jig (used for resectioning portions of the femur and tibia). Delp et al. Patent, col. 15, lines 31 – 47; col. 18, lines 53 – 55; and col. 20, lines 58 – 62. The CMM is used to position the femoral jig or tibial jig on the femur or tibia respectively for resectioning. To facilitate positioning the femoral and tibial jigs, the CMM provides data to an associated computer regarding the “pose” of the femoral jig, tibial jig or other attached components. Delp et al. does not disclose another method for positioning the jigs, or any other total knee arthroplasty instrument. Moreover, Delp et al. does not teach, suggest or disclose associating one or more fiducials with either the femoral jig, tibia jig or any other instrument used with the CMM. Because Delp et al.

does not teach a surgical instrument attached to a fiducial, Delp et al. does not teach each and every element of claims 1 – 6, 8 and 10 – 14.

Claim 16 requires a “total knee arthroplasty trial component attached at least indirectly to a fiducial.” Delp et al., however, does not teach, disclose or suggest a total knee arthroplasty trial component attached to a fiducial. Like the femoral and tibial jigs, Delp et al. teaches using the CMM to confirm the correct positioning of the implanted components. Delp et al. Patent, col. 21, lines 55 – 59. Moreover, Delp et al. does not disclose attaching the CMM to the trial component, but rather teaches “sampling” points on the trial component using the CMM after the trial component has been installed. *Id.* Because Delp et al. does not teach attaching a total knee arthroplasty trial component with a fiducial, Delp et al. does not teach each and every element of claims 16 – 20.

Because Delp et al. does not teach each and every element of any of claims 1 – 6, 8, 10 – 14 and 16, Delp et al. does not anticipate any of claims 1 – 6, 8, 10 – 14 and 16. The undersigned respectfully requests the Examiner to reconsider and withdraw the §102(b) rejections of claims 1 – 6, 8, 10 – 14 and 16.

### §103 REJECTIONS

The Office Action, on pages 5 – 7, rejected claims 9, 15 and 17 – 20 under 35 U.S.C. §103. On pages 5 – 6, the Office Action rejected claims 15 and 17 under §103 as unpatentable over Delp et al. in view of Gustilo et al. On pages 6 – 7, the Office Action rejected claims 9, 18, 19 and 20 under §103 as unpatentable over Delp et al. in view of Foley et al. Applicants respectfully traverse these rejections and request reconsideration and withdrawal thereof.

To establish a *prima facie* case of obviousness, three criteria must be met. First, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the references or to combine reference teachings. Second, there must be

a reasonable expectation of success. Finally, the prior art references when combined must teach or suggest all the claim limitations. See M.P.E.P. § 2142.

Here, none of the cited references teach, suggest or disclose, alone or in combination, all the claim limitations of the rejected claims. Claims 9 and 15 depend from Claim 8, which includes the limitation of a "total knee arthroplasty surgical instrument attached to a fiducial." Claim 17 includes the limitation of "a total knee arthroplasty implant trial component attached at least indirectly to a fiducial." Claim 18 and Claim 19, which depends from claim 18, include the limitation of "a total knee arthroplasty implant component attached at least indirectly to a fiducial." Claim 20 includes the limitation of "a total knee arthroplasty implant component attached to a tool to which is attached a fiducial." None of Delp et al., Gustilo et al. or Foley et al. teach, suggest or disclose, alone or in combination, a total knee arthroplasty instrument / component associated at least indirectly with a fiducial.

As discussed above, Delp et al. does not teach, suggest or disclose associating a total knee arthroplasty instrument / component associated with a fiducial. Rather, Delp. et al. teaches the use of a robotic arm (CMM) for positioning various jigs used in total knee arthroplasty.

Nor does Gustilo et al. teach, suggest or disclose associating a total knee arthroplasty instrument / component with a fiducial. Gustilo et al. discloses an adjustable knee arthroplasty trial prosthesis. Gustilo et al., however, does not disclose associating the adjustable knee arthroplasty trial prosthesis with a fiducial.

Finally, Foley et al. discloses apparatus and methods for use in computer-assisted spinal surgery. Although Foley et al. teaches a spinal instrument attached to a fiducial, it does not teach or suggest associating a total knee arthroplasty instrument / component with a fiducial. Spinal surgeries and total knee arthroplasty surgeries are two very different procedures, each requiring specialized knowledge of the unique difficulties and specific procedures necessary to carry them out. Nothing

in Foley et al. suggests associating a fiducial with a total knee arthroplasty instrument / component.

In rejecting claims 9 and 18 – 20 as unpatentable over Delp et al. in view of Foley et al., the Examiner stated on Page 6:

Since Delp includes fiducials attached to both the trial component and the body, it would have been obvious to one of ordinary skill in the art at the time the invention was made to include in the process of Delp the steps of (a) discontinuing tracking with the trial component fiducial and (b) initiating tracking with the body part fiducial, as Foley teaches that this is another way to track a surgical component in image-guided surgery.

As discussed above, however, the undersigned respectfully disagrees with the Examiner. Delp et al. does not disclose “fiducials attached to both the trial component and the body,” it only discloses associating fiducials with the patient’s anatomy, not fiducials attached to a trial component. Delp et al. Patent, col. 18, lines 2 – 16. Moreover, the fiducials attached to the patient’s anatomy must be tracked using the same CMM apparatus discussed above. *Id.*


Because none of Delp et al., Gustilo et al. and Foley et al., alone or in combination, teach, suggest or disclose a total knee arthroplasty instrument / component associated at least indirectly with a fiducial, the references cited do not teach or suggest all the claim limitations of the rejected claims. As such, the undersigned respectfully requests the Examiner to reconsider and withdraw the §103 rejections to the claims.

### CONCLUSION

In light of the above amendments and remarks, the undersigned is of the opinion that the Office Action has been completely responded to and that the application is now in condition for allowance. Such action is respectfully requested.

If the Examiner believes any informalities remain in the application that may be corrected by Examiner's Amendment, or there are any other issues that can be resolved by telephone interview, a telephone call to the undersigned attorney at (404) 815-6291 is respectfully solicited.

Respectfully submitted,



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